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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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EXAMINER

FRENEL, VANEL

ART UNIT PAPER NUMBER

3626

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,366

Applicant(s)

HESS, CATHY ILYSE

Examiner

Vanel Frenel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to Amendment filed on 01/18/05. Claims 1, 3, 9, 15 and 17-19 have been amended. Claims 2, 12 and 14 have been canceled. Claims 1, 3-11, 13, 15-19 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 9, 15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511), Hennessy et al (6,277,071) in view of Closed Dressings After Skin Resurfacing by James P. Newman R. James Koch, Richard L. Goode, Archives of Otolaryngology-Head & Neck Surgery, Chicago: July 1998. Vol.124, Issue 7; Pgs.751-758 and further in view of Pressure ulcers: Causes, risk factors, assessment, and intervention by (Mary Arnold Andrychuk. Orthopedic Nursing. Pitman: July/Aug 1998. Vol.17, Iss.4; Pg.65; 18 pgs).

(A) Claim 1 has been amended to recite the limitation of: "by applying a risk assessment tool comprising a rating scale to objectively characterize a subjective condition of a patient's skin and wound thereby".

The combination of Dang, Hennessy, Gibson and James do not explicitly disclose "by applying a risk assessment tool comprising a rating scale to objectively characterize a subjective condition of a patient's skin and wound thereby".

However, this feature is known in the art, as evidenced by Andrychuk. In particular, Andrychuk teaches by applying a risk assessment tool comprising a rating scale to objectively characterize a subjective condition of a patient's skin and wound thereby" (See Andrychuk, Page 1, Paragraph 3; Page 10; Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Andrychuk within the collective teachings of Dang, Hennessy, Gibson and James with the motivation of providing a thorough patient assessment, including risk factors, health history, and wound presentation, must occur prior to determining a plan care thereby effectively treating wounds (See Andrychuk, Page 2, Paragraph 4; Page 1 in Abstract).

(B) Claim 3 is slightly amended to only change the dependency.

(C) Claim 9 has been amended to recite the limitations of "from a patient at bedside by applying a risk assessment tool comprising a skin and wound rating scale including a decision guide that provides a plurality of descriptors for use in objectively characterizing the subjective condition of a patient's skin and wound thereby".

The combination of Dang, Hennessy, Gibson and James do not explicitly disclose "from a patient at bedside by applying a risk assessment tool comprising a skin

and wound rating scale including a decision guide that provides a plurality of descriptors for use in objectively characterizing the subjective condition of a patient's skin and wound thereby".

However, this feature is known in the art, as evidenced by Andrychuk. In particular, Andrychuk teaches "from a patient at bedside by applying a risk assessment tool comprising a skin and wound rating scale including a decision guide that provides a plurality of descriptors for use in objectively characterizing the subjective condition of a patient's skin and wound thereby" (See Andrychuk, Page 1, Paragraph 3; Page 10; Paragraphs 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Andrychuk within the collective teachings of Dang, Hennessy, Gibson and James with the motivation of providing a thorough patient assessment, including risk factors, health history, and wound presentation, must occur prior to determining a plan care (See Andrychuk, Page 2, Paragraph 4).

(D) Claim 17 has been amended to recite the limitations of: "by applying a Braden Scale risk assessment to a patient to objectively characterize the subjective condition of said patient's wound thereby".

The combination of Dang, Hennessy, Gibson and James do not explicitly disclose "by applying a Braden Scale risk assessment to a patient to objectively characterize the subjective condition of said patient's wound thereby".

However, this feature is known in the art, as evidenced by Andrychuk. In particular, Andrychuk teaches "by applying a Braden Scale risk assessment to a patient to objectively characterize the subjective condition of said patient's wound thereby" (See Andrychuk, Page 10, Paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Andrychuk within the collective teachings of Dang, Hennessy, Gibson and James with the motivation of providing a thorough patient assessment, including risk factors, health history, and wound presentation, must occur prior to determining a plan care (See Andrychuk, Page 2, Paragraph 4).

(E) Claim 18 has been amended to recite the limitations of: "by applying a risk assessment tool to an affected region of a patient's body comprising a skin and wound rating scale to objectively characterize the subjective condition of said affected region thereby".

The combination of Dang, Hennessy, Gibson and James do not explicitly disclose "by applying a risk assessment tool to an affected region of a patient's body comprising a skin and wound rating scale to objectively characterize the subjective condition of said affected region thereby".

However, this feature is known in the art, as evidenced by Andrychuk. In particular, Andrychuk teaches "by applying a risk assessment tool to an affected region of a patient's body comprising a skin and wound rating scale to objectively characterize

the subjective condition of said affected region thereby" (See Andrychuk, Page 10, Paragraphs 3-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Andrychuk within the collective teachings of Dang, Hennessy, Gibson and James with the motivation of providing a thorough patient assessment, including risk factors, health history, and wound presentation, must occur prior to determining a plan care (See Andrychuk, Page 2, Paragraph 4).

(F) Claim 19 has been amended to recite the limitations of "by applying a Braden Scale risk assessment tool to a patient comprising a skin and wound rating scale including a decision guide that provides a plurality of descriptors and a numeric rating for use in objectively characterizing the subjective condition of said patient's skin and wound thereby".

The combination of Dang, Hennessy, Gibson and James do not explicitly disclose "by applying a Braden Scale risk assessment tool to a patient comprising a skin and wound rating scale including a decision guide that provides a plurality of descriptors and a numeric rating for use in objectively characterizing the subjective condition of said patient's skin and wound thereby" (See Andrychuk, Page 10, Paragraphs 3-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Andrychuk within the collective teachings of Dang, Hennessy, Gibson and James with the motivation of providing a thorough patient

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assessment, including risk factors, health history, and wound presentation, must occur prior to determining a plan care (See Andrychuk, Page 2, Paragraph 4).

(G) Claims 4-8, 10-11, 13 and 16 have not been amended are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

Response to Arguments

4. Applicant's arguments on 01/18/05 with respect to claims 1, 3, 9, 15, and 17-19 have been considered but are moot in view of the new ground(s) of rejection.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

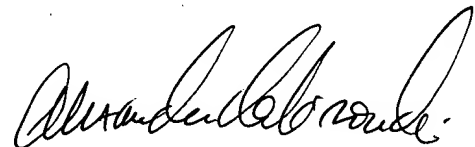
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not the applied art teaches Organizing for skin care: A case history by Knox Leila: Nursing Homes. Cleveland: Mar 1996.Vol.45, Iss.3; pg.33, 1 pg).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 571-272-6769. The examiner can normally be reached on Monday- Thursday from 6:30 am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
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ALEXANDER KALINOWSKI
PRIMARY EXAMINER

April 17, 2005